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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
NEWARK DIVISION

Case No: 2:20-cv-08030-SDW-LDW

RUTH LARA, Individually and
as Guardian of her minor child J.S.,
on behalf of themselves and on behalf
of those similarly situated,

Plaintiffs,

v.

PUFF BAR, NICK MINAS,
PATRICK BELTRAN, COOL CLOUDS
DISTRIBUTION, INC.,
UMAIS ABUBAKER,
and SHAHID SHAIKH,

Defendants.
_____/

PLAINTIFFS' RESPONSE IN OPPOSITION TO DEFENDANT, PUFF BAR'S MOTION TO DISMISS SECOND AMENDED COMPLAINT

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Plaintiffs, Ruth Lara, individually, and as legal Guardian of her minor child, J.S., on behalf of themselves and on behalf of those similarly situated, by and through undersigned counsel, submit this Response in Opposition to Defendant, Puff Bar's Motion to Dismiss Second Amended Complaint.

I. BACKGROUND AND SUMMARY OF ALLEGATIONS

A. Puff Bar, A Salt-Nicotine Delivery Device, Is Unreasonably Dangerous.

The Puff Bar e-cigarette is a disposable pod device. Each Puff Bar uses nicotine salts—a formula that allows for much higher levels and efficient delivery of nicotine with less irritation compared to earlier generations of e-cigarettes. Nicotine strength can be as high as 5% in Puff Bars. Second Amended Complaint "SAC" at ¶ 36. Defendants engineered an e-cigarette device capable of delivering more nicotine and fueling higher levels of consumer addiction than most prior versions of e-cigarettes and combustible cigarettes.

Defendant heavily promoted and marketed its highly addictive product that is ***on the market illegally*** to youth as healthy, safe, cool and available in kid-friendly flavors. *Id*. at ¶ 38. E-cigarette manufacturers like Puff Bar learned that a nicotine salt formulation would maximize buzz and minimize harshness. *Id*. at ¶ 41. Dramatically reducing the throat hit is not necessary for a product that is aimed at smokers, who are accustomed to the harshness of cigarette smoke, but it effectively appeals to nonsmokers, especially youth. The cigarette industry has long recognized this; a published study of industry documents concluded that "product design changes which make cigarettes more palatable, easier to smoke, or more addictive are also likely to encourage greater uptake of smoking."[1] *Id*. at ¶ 42.

[1] David A. Kessler, *Juul Says It Doesn't Target Kids. But Its E-Cigarettes Pull Them In*, N.Y. TIMES (July 31, 2019), https://www.nytimes.com/2019/07/31/opinion/juul-kids.html.

Puff Bar's website represented that the "Original Puff Bar [is] equivalent to one pack of 20 cigarettes."[2] *Id*. at ¶ 114. However, Dr. Bonnie Halpern Felsher, a developmental psychologist at Stanford University, has conducted research that found that one Puff Bar has about 300 puffs and can contain about as much nicotine as *two or three packs of cigarettes.*[3] *Id*. at ¶ 115. Defendants also knew that the use of nicotine salts facilitates absorption of nicotine across biological membranes. Puff Bar's e-liquid formulation is highly addictive not only because it contains a high concentration of nicotine, but because it contains a particularly potent form of nicotine—i.e., nicotine salts. *Id*. at ¶ 117.

B. Puff Bar Marketed to Youth Without Warning of the Risks of Addiction.

Adolescents using vaping devices that contain nicotine are developing dependence to the products. Experts specializing in nicotine addiction have studied the correlation between vaping and dependence in adolescents and found that the level of e-cigarette addiction correlates significantly with their level of nicotine exposure.[4] *Id*. at ¶ 80. Kids are particularly vulnerable to nicotine addiction. As described by the United States Surgeon General, "Tobacco use is a pediatric epidemic." Nine out of ten smokers begin by age 18 and 80% who begin as teens will smoke into adulthood.[5] *Id*. at ¶ 86.

More than 80% of underage smokers choose brands from among the top three most heavily advertised.[6] *Id*. at ¶ 57. Youth marketing was critical to the success of cigarette companies. In the

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[2] *Everything You Ever Wanted to Know About the Puff Bar Disposable Device*, PUFF BAR FAQ: WHAT IS A PUFF BAR, https://puffbar.com/blogs/vape-news/puff-bar-101-everything-you-ever-wanted-to-know-about-the-puff-bar-disposable-device (last visited June 25, 2020).

[3] *Parents: Teens Are Still Vaping, Despite Flavor Ban. Here's What They're Using*. https://www.npr.org/sections/health-shots/2020/02/17/805972087/teens-are-still-vaping-flavors-thanks-to-new-disposable-vape-pens (last visited June 26, 2020).

[4] Vogel EA, Prochaska JJ, Rubinstein M., *Measuring E-Cigarette Addiction Among Adolescents*, TOBACCO CONTROL, https://tobaccocontrol.bmj.com/content/early/2019/05/10/tobaccocontrol-2018-054900.full.

[5] *Preventing Tobacco Use Among Youth and Adults: A Report of the Surgeon General*, at 1 (2012), https://www.hhs.gov/surgeongeneral/reports-and-publications/tobacco/index.html.

[6] *Preventing Tobacco Use Among Youths, Surgeon General Fact Sheet*, https://www.hhs.gov/surgeongeneral/reports-and-publications/tobacco/preventing-youthtobacco-use-factsheet/index.html (last visited Dec. 9, 2019).

1950s, Philip Morris USA, Inc., for example, intentionally marketed cigarettes to young people as a pool from which to "replace smokers" to ensure the economic future of the cigarette industry. *Id*. at ¶ 59. The landmark *USA v. Philip Morris*, 449 F. Supp. 2d 1 (D.D.C. 2006) case revealed that tobacco companies targeted adolescents for decades by: "(1) employ[ing] the concept of peers in order to market to teenagers; (2) us[ing] images and themes in their marketing that appeal to teenagers; and (3) employ[ing] advertising and promotion strategies to knowingly reach teenagers." In terms of images and themes that cater to adolescents, the court found "overwhelming" evidence that tobacco companies intentionally exploited adolescents' vulnerability to imagery by emphasizing themes of "independence, adventurousness, sophistication, glamour, athleticism, social inclusion, sexual attractiveness, thinness, popularity, rebelliousness, and being 'cool.'" *Id*. at ¶ 65. Cigarette companies have also known for decades that flavored products are key to nicotine adoption by youth. *Id*. at ¶ 66. A 1972 Brown & Williamson internal memorandum titled "Youth Cigarette—New Concepts," observed that "it's a well-known fact that teenagers like sweet products."[7] *Id*. Puff Bar has emulated this approach, deploying these advertising tactics on today's major social media outlets used by adolescents, including YouTube, TikTok, Instagram, and Reddit. *Id*. at ¶ 67, 74. Puff Bar's collection of fruit flavors epitomizes health and is hardly suggestive of addiction and health harm. *Id*. at ¶ 69.

Puff Bar products contain and deliver more nicotine than is represented, are delivered by heat vaporization inhaled into the body, and contain and deliver other harmful products that injure multiple organ systems and are designed to cause nicotine addiction. *Id*. at ¶ 136. And yet they are marketed to youth and made accessible to youth without adequate nicotine warnings. *Id*. at ¶ 146.

[7] Brown & Williamson official A.J. Mellman, (1983) *Tobacco Industry Quotes on Nicotine Addiction*, www.ok.gov/okswat/documents/Tobacco%20Industry%20Quotes %20on%20Nicotine%20Addiction.pdf (as of Oct. 15, 2019).

Puff Bar products are sold in a defective condition that is unreasonably dangerous and unsafe to the consumer because the Defendants failed to warn of the risk of nicotine addiction and its severe adverse health effects such as increased risk of lung injuries, seizure, strokes, heart attacks, cardiovascular injuries, behavioral, cognitive and mental health injuries. *Id*. at ¶ 147. Rather Puff Bar offers its product in a variety of kid-friendly flavors including Sour Apple, Cool Mint, Blue Razz, Pink Lemonade, to name a few. These efforts, coupled with cross-platform social media campaigns, caused Puff Bar to go viral.

Ironically, Defendant makes the argument that Plaintiffs purchased its product "illegally" and thus, for all intents and purposes, could not be regarded as an "ordinary" consumer. All the while, Defendant continues heavily promoting and marketing ***its product that is on the market illegally*** to young people—positioning itself to reap all of the profits but none of the liability.

II. ARGUMENT

A. The Food, Drug, and Cosmetic Act Does Not Preempt Plaintiffs' Claims.

1. This Court Must Presume Against Federal Preemption of Historic State Police Powers.

Puff Bar argues incorrectly that the Federal Food, Drug, and Cosmetic Act ("FDCA") preempts Plaintiffs' claims under state consumer protection laws. Federal preemption must be narrowly construed; it exists only if the language of the statute demonstrates a congressional intent to preempt. *Cipollone v. Liggett Group, Inc*., 505 U.S. 504, 523 (1992) ("[W]e must … narrowly construe the precise language of [the statute] and we must look to each of petitioner's common law claims to determine whether it is preempted").[8] In fields traditionally occupied by the states

[8] Although all preemption turns on statutory language, a federal statute need not expressly state that it preempts state law. A statute can also impliedly preempt state law, if Congress demonstrates an intent that federal law "occupy the field" (i.e., "field preemption") or "where it is impossible for a private party to comply with both state and federal law." (i.e. "conflict preemption"). *Crosby v. National Foreign Trade Council*, 530 US 363, 372-73 (2000); *Jones v. Rath Packing Co*., 430 U. S. 519, 525 (1977).

such as the exercise of a state's police powers, the "presumption against preemption is heightened, *Riegel v. Medtronic*, Inc., 552 U.S. 312, 334 (2008) (citation omitted), and Congress' intent to preempt state law must be "clear and manifest." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996); *see also Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (reiterating Medtronic's presumption against preemption).

The strong presumption against preemption applies both to the question of whether Congress intended to preempt state law and to the scope of preemption. *See Medtronic*, 518 U.S. at 485. Congress' intent "primarily is discerned from the language of the preemption statute and the 'statutory framework' surrounding it." *Lohr*, 518 U.S. at 485–86. "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–67 (1989). Even "[i]f a federal law contains an express pre-emption clause, it does not immediately end the inquiry, because the question of the substance and scope of Congress displacement of state law still remains." *Altria Group, Inc. v. Good*, 555 U.S. 70, 76 (2008). Consumer protection laws such as the unfair competition law ("UCL"), false advertising law ("FAL"), and CLRA, and laws regulating the marketing of cigarettes and tobacco products, including the prevention of deceptive sales practices, are all within the states' historic police powers, and thus are subject to the strong presumption against preemption. *See, e.g., In re Tobacco Cases II, Tobacco Cases II*, 46 Cal.4th 298, 327–28 (2009) (tobacco advertising subject to UCL); *Mangini v. R. J. Reynolds Tobacco Co.*, 7 Cal. 4th 1057, 1073–74 (1994) (no preemption of tobacco advertisements targeting youth).

2. Congress Expressly Limited Preemption Under the Tobacco Control Act.

The Tobacco Control Act leaves no doubt that Congress was aware of, and left intact, States' power to regulate the sale and marketing of tobacco products using consumer protection laws. Congress passed the TCA based on findings that "tobacco company continue to target and market to youth . . . encourage youth to start smoking . . . . and designed their cigarettes to precisely control nicotine delivery levels and provide doses of nicotine sufficient to create addiction while also concealing much of their nicotine-related research." TCA, Findings (47)–(49) (citing *USA v Philip Morris*, No. 99-cv-2496 (D.D.C. Aug. 17, 2006). Indeed, the portion of the TCA Defendants cites as preemptive, 21 U.S.C. §387p, is actually titled "***Preservation of State and Local Authority***." The section has a narrow preemption provision, 21 U.SC. § 387p(a)(2)(A), sandwiched between a host of express limitations on this preemption. *Id.* § 387p(a)(1), (a)(2)(B), (b), and there are two other provisions that provide even further limitation on preemption. *Id.* § 387h. In the narrow preemption section Defendant relies on, "PREEMPTION OF ***CERTAIN*** STATE AND LOCAL REQUIREMENTS," (emphasis added), Congress provided that no state may:

> establish or continue in effect with respect to a tobacco product any requirement ***which is different from, or in addition to,*** any requirement under the ***provisions of this subchapter relating to*** tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.

U.S.C. § 387p(a)(2)(A) (emphasis added). In the next subsection, titled "EXCEPTION," Congress narrowed the scope of its limited preemption with a broad savings clause:

> Subparagraph A ***does not apply to requirements relating to the sale, distribution,*** possession, information reporting to the State, exposure to, ***access to, the advertising and promotion of,*** or use of, tobacco products by individuals of any age, or relating to fire safety standards for tobacco products.

Id. § 387p(a)(2)(B) (emphasis added). And in the immediately preceding subsection to the "PREEMPTION" section, in a section entitled "PRESERVATION," Congress stated, "Except as provided in [the limited preemption section] a state ***may*** "enact, adopt, promulgate and enforce any law, rule, regulation or other measure with respect to tobacco products" ***even if*** such law "is in addition to, or more stringent than, requirements under this subchapter." 21 U.S.C. § 387p(a)(1). In the final subsection, "RULE OF CONSTRUCTION REGARDING PRODUCT LIABILITY," the statute specified that "[n]o provision of this subchapter relating to a tobacco product shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." *Id.* § 387p(b). Congress also included another separate section involving preemption; it gave the FDA authority to regulate tobacco products while simultaneously providing "NO EXEMPTION FROM OTHER LIABILITY. Compliance with an order [of the FDA] issued under this section shall not relieve any person from liability under Federal or State law." *Id.* § 387h(b).

The legislative history of the TCA establishes that Congress intended to preempt only state laws that were *specific to tobacco*, not general false advertising and consumer-protection laws. The House Committee Report on the bill stated that the bill "would preempt ***state laws governing tobacco products.***" House Committee Rep. 111-58, pt. 1, at 25. The Congressional Budget Office Report similarly concluded that the bill would only preempt "***certain state laws governing tobacco products***." This interpretation of the TCA comports with the Supreme Court's prior recognition of a distinction between tobacco-specific requirements preempted by the Federal Cigarette Labeling and Advertising Act ("FCLAA"), and generalized duties of care that were not preempted by that statute. *See Cippolone*, 505 U.S. at 531 ("This indicates that Congress intended the phrase 'relating to smoking and health' . . . to be construed narrowly, so as not to proscribe the regulation

of deceptive advertising"). Indeed, in section 203 of the TCA, Congress repeated the same reference to preemption of only "smoking and health" regulations. 15 U.S.C. § 1334.

3. Plaintiffs' Design-Related Claims are Expressly Not Preempted.

Puff Bar glosses over the TCA's preservation clause, 21 U.S.C. § 387p(a)(1), exceptions from preemption, *id.* § 387p(a)(2)(A), and its rule of construction, *id.* § 387p(a)(2)(B), which cover the overwhelming majority of Plaintiff's claims. Subsection (b) makes clear that all of Plaintiffs' "product liability" claims are expressly *not* preempted. *Id.* § 387p(b). Defendant cannot reasonably argue otherwise. Accordingly, at a minimum, all the causes of action in the Complaint survive to the extent they are based on product liability.

4. The FDCA Does Not Preempt Plaintiffs' Claims Arising from Warnings and Labeling.

Defendant is left to argue that portions of Plaintiffs' consumer claims that seek to enforce state laws relating to "warnings" and "labeling" of the Puff Bar product are expressly preempted because they impose requirements that are "additional" or "different" to those of the FDCA. 21 U.S.C. §387p(a)(2)(A). This argument fails for four reasons.

First, as noted above, Congress' intent was only to narrowly preempt *tobacco-specific* laws that imposed "different" or "additional" requirements on tobacco products, not laws of general applicability like those under which Plaintiffs have sued. Congress adopted a very narrow preemption provision sandwiched between express non-preemption provisions and accompanied by reuse of the same language regarding "smoking and health" regulations, after the Supreme Court's opinion in *Cippolone* had already distinguished between specific laws about tobacco (preempted) and general advertising laws (not preempted). By reusing that language after *Cippolone*, Congress is presumed to have agreed to and adopted the framework. *Lamar, Archer & Cofrin, LLP v. Appling*, 138 S. Ct. 1752, 1762 (2018) ("When administrative and judicial

interpretations have settled the meaning of an existing statutory provision, repetition of the same language in a new statute indicates, as a general matter, the intent to incorporate its administrative and judicial interpretations as well.").

Second, even if Congress had intended to preempt more general state laws, none of the state laws under which Plaintiffs sue would impose any such "different" or additional" requirements from the TCA. The TCA provides that "[a] tobacco product shall be deemed to be misbranded if its labeling is ***false or misleading*** in any particular." *Id.* § 387c(a)(1) (emphasis added). The state consumer laws that Plaintiffs seek to enforce have the *identical standard.* Myriad cases have held that these same state consumer laws are not preempted by other federal statues that have identical "different from or in addition to" preemption language, and an identical bar against "false or misleading" labeling, including the Food Drug and Cosmetics Act (of which the TCA is a part) and the Medical Device Act. *See, e.g.*, *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 758 (9th Cir. 2015) (Thus, "if [Plaintiffs'] suit ultimately requires [defendant] to remove these allegedly misleading advertising statements from its product labels, such a result does not run afoul of the FDCA, which prohibits 'requirement[s]' that are 'different from,' [or] 'in addition to' or 'not identical with' federal rules.").

Third, even if there were preemption of some laws, it would only bar claims for conduct occurring after the allegedly preemptive FDA rules took effect on August 10, 2018. Defendant argues that preemption starts on the date that the FDA "deemed" that Electronic Nicotine Delivery Systems ("ENDS") would be subject to the TCA, May 10, 2016, not the date that ENDS labeling requirements actually did become effective *two-and-one half years later*. But neither Congress nor the FDA intended to exempt ENDS before any substantive federal regulations were in effect.

Finally, Defendant has not satisfied the requirements of the premarket approval process, which are the *specific federal requirements giving rise to preemption*. In the TCA, Congress enacted detailed provisions regarding premarket approval, which should be read in conjunction with preemption provisions, just as they have been in another FDA-entrusted statute, the Medical Device Act. There is no basis to infer Congressional intent to supplant state law while at the same time permitting manufacturers to make any label claims they wish, without obtaining FDA approval.

a. Because Plaintiffs' labeling claims parallel Federal requirements, they are not preempted.

Preemption "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel v. Medtronic*, 552 U.S.at 330; *Lohr v. Medtronic*, 518 U.S. at 495 (nothing in the Medical Device Act's preemption clause "denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements"); *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1231 (9th Cir. 2013) (reversing district court dismissal of failure-to-warn claim on preemption grounds). State law labeling requirements are only expressly preempted if: (1) the Federal Government has established labeling requirements, *and* (2) Plaintiffs' state law claims arising are based on labeling requirements or that are "different from, or in addition to," the federal requirements. *See Riegel*, 552 U.S. at 322.

Plaintiffs allege that Puff Bar breached general state-law duties to not advertise its products in a manner that was misleading or untrue. The same standard already exists in the federal law. *Compare* TCA § 903(a)(7) (false or misleading statements in advertisements constitute misbranding), *with* N.J. Stat. Ann. § 56:8-2 (it is unlawful to use deception, fraud, false promise, or misrepresentation in connection with the sale or advertisement of any merchandise).

There is no reason to believe that Congress intended to allow tobacco product sellers to violate state laws against misleading and deceptive labeling by omitting this crucial information from consumers for *nearly ten years* since the TCA was adopted in 2009, until whatever date federal regulations might go into effect. To the contrary, Congress intended that even *after* the FDA adopted regulations under the TCA, "[c]ompliance with an order [of the FDA] issued under this section shall not relieve any person from liability under Federal or State law." 21 U.S.C. § 387h(b). Similarly, the FDA made clear that it did not intend the ENDS regulations to be a complete list of required label statements. Nor could it, because the TCA bars all labeling that is "false or misleading in any particular." *Id.* § 387c(a)(1). The FDA therefore entitled its ENDS rules "*Minimum* Required Warning Statements," 21 C.F.R. § 1143 (emphasis added), adding the word "minimum" to convey that the FDA does "not preclude other health warnings" and to "clarify that part 1143 is not intended to prevent product manufacturers from including truthful, non-misleading warnings on their products' packaging or advertisements voluntarily." 21 CFR 28990. As such, compliance with general state law requirements imposes no "additional" or "different" requirements from the TCA or the federal regulations, because the TCA already requires, and the regulations already contemplate, that manufacturers must refrain from deceptive conduct.

In similar situations, courts have held that state law duties to warn survive implied preemption, as the "general obligation[]" to warn is "no more a threat to federal requirements than would be a state law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force." *Stengel*, 704 F.3d at 1229 (quoting *Lohr*, 518 U.S. at 501–02). Even in the context of drugs, where the FDA has authority over all the aspects of the drug label, the manufacturer is required to update the label with appropriate warnings of known risks. *Wyeth*, 555 U.S. at 572. When FDA regulations permit manufacturer to unilaterally

update safety warnings on their labels—as is true for both pharmaceuticals and ENDS—the FDA's intent is to "to make it clear that manufacturers remain responsible for updating their labels," and the fact that the label otherwise complies with FDA regulations, or even has been pre-approved by the FDA, does not shield the manufacturer from state law liability. *Id.* at 573. Rather, preemption is a defense only if it would be *impossible* to comply with both the state-law duties and the federal requirements, "and impossibility preemption is a demanding defense." *Id.*[9]

Puff Bar cites *In re Fontem*, 2016 U.S. Dist. LEXIS 187853, at *20 (C.D. Cal. Nov. 1, 2016)—an unpublished case that has not been followed or relied upon by any other court—as authority for its position that it was free to sell misbranded products and violate its duty to warn. *Fontem* held that the TCA preempted state law claims for failures to warn of formaldehyde on tobacco product labels, despite the lack of any applicable federal regulations. *Id*. at *4–5. *Fontem* mistakenly concluded that the preservation clause of § 387p(a)(2)(B) was limited to "exposure to" or "use of" tobacco products, even though that section's clear language also preserves state power to police the "sale, distribution, . . . advertising and promotion of" tobacco products. *Fontem* also ignored the express limitations on preemption, the implicit adoption of the *Cipollone* framework, the similar framework under the FDCA (*see supra*) and the Medical Device Act (*see infra*), and all the legislative history discussed above. *Fontem's* holding is inconsistent with Supreme Court precedent on how preemption should be analyzed,and it should not be followed.

Puff Bar—*and Fontem*—ignored, *In Greene v. Five Pawns, Inc.*, 2016 U.S. Dist. LEXIS 187866 (Aug. 30, 2016), a nearly identical case that held the TCA preempts state laws only to the

[9] Other federal regulations that provide minimum guidelines also provide no basis for federal preemption. *See Sprietsma v. Mercury Marine*, 537 U.S. 51, 67–68 (2002) (Federal Boat Safety Act did not preempt common-law tort claims, arising out of failure to install propeller guards on motor-boat engines); *Bates v Dow Agrosciences LLC*, 544 U.S. 431, 499 (2005) (Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) did not preempt claims for defective design, defective manufacture, negligent testing, breach of express warranty, and violation of Texas Deceptive Trade Practices Act.

extent they are in direct conflict with FDA rules. In *Greene*, the plaintiffs brought claims arising out of unlabeled chemicals other than nicotine in ENDS e-liquids. In denying defendant's express preemption argument, the court determined that the TCA's prohibition on misbranded tobacco products—i.e., products with false or misleading labels—were preempted only to the extent that they conflicted with the TCA's labeling requirements. *Greene*, at *20-24. But the court followed the Ninth Circuit's preemption analysis in *Astiana*, and left the question of whether plaintiffs proposed labeling requirements were "different from, or in addition to," the TCA's labeling requirements for the jury to decide. *Greene*, at *24.

Defendant argues that recent cases in the Ninth Circuit, namely *Colgate v. JUUL Labs, Inc.*, have held that state consumer protection act claims based on alleged omissions are preempted under Section 916 of the FDCA. 345 F. Supp. 3d 1178, 1188 (N.D. Cal. 2018). But *Colgate* largely cuts against Defendant's preemption argument. In *Colgate*, the court held the state consumer protection act and state common law claims premised on Juul's alleged misrepresentations by omission, as opposed to alleged mislabeling or fraudulent advertising, were expressly preempted by Section 916 and the FDA rule on labeling. Addressing claims of "omission", Defendant intentionally overlooks *Colgate's* rulings on claims of mislabeling. Specifically, Judge Orrick denied JUUL's argument that the product liability claims—notably those concerning mislabeling—were preempted by the Tobacco Control Act ("TCA"), 21 U.S.C. § 387. [*Colgate* Doc. 66, at 11] ("Plaintiffs' causes of action based on advertisements or the mislabeling of the amount of nicotine contained in each pod are not preempted by the TCA."). *Colgate, et al. v. JUUL Labs, Inc.*, 3:18-cv-02499-WHO.

Judge Orrick reaffirmed this ruling in *In re JUUL Labs, Inc. Marketing, Sales Prac. & Prod. Liab. Litig.*, MDL 2913 [Doc. 1084, at 19] ("[T]he vast majority of plaintiffs' claims may

proceed now. No claims other than the false and misleading claims based on failure to disclose nicotine addictiveness on labels of JLI's products are preempted."); *see also id.* at 30 ("The Retailer Defendants' motion to dismiss based on express preemption is DENIED."); *see also id.* at 33 ("Defendants' motions to dismiss based on [implied] preemption are DENIED.").

b. Because Puff Bar has not satisfied premarket review requirements, the TCA requirements giving rise to preemption have not been met.

The labeling claims also are not preempted because Puff Bar never sought or received approval from the FDA for its label statements. Under the Medical Device Act, which contains a nearly-identical three-tiered premarket review process as the TCA and a nearly-identical preemption clause as the TCA, premarket review is required for life-sustaining medical devices or devices that pose unreasonable risks of death. For these devices, premarket review of the "design, manufacture, and labeling of the device, as approved by the FDA as safe and effective after the device has undergone the [premarket approval process], *are the specific federal requirements giving rise to preemption*." *Steele v. Collagen Corp.*, 54 Cal. App. 4th 1474, 1489 (1997).[10] Medical devices that do not undergo premarket review do not receive the benefit of the Medical Device Act's preemption of state law requirements. *See, e.g.*, *Riegel*, 555 U.S. at 322-33 (2008); *Committee of Dental Amalgam Mfgs. & Dists. v. Stratton*, 92 F.3d 807, 813-14 (9th Cir. 1996) (Proposition 65 claim not preempted by MDA because product did not undergo premarket review).

Since then, courts have consistently analyzed preemption under the MDA by asking: has the device received premarket authorization, and if so are the state law requirements at issue "different from, or in addition to" the Medical Device Act's requirements? *See, e.g.*, *La Paz v.*

[10] Through premarket review, "the federal government, it can truly be said, has 'weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.'" *Mitchell v. Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997).

Bayer Healthcare LLC, 159 F. Supp. 3d 1085, 1091 (N.D. Cal. 2016); *Funke v. Sorin Grp. USA, Inc.*, 147 F. Supp. 3d 1017, 1023 (C.D. Cal. 2015) (same). The TCA, like the MDA, contains exhaustive premarket review requirements to weigh the risks the new tobacco products pose. *See Philip Morris USA Inc. v. United States FDA*, 202 F. Supp. 3d 31, 38–39 (D.D.C. 2016) ("a 'new tobacco product' must first receive FDA approval before it can be introduced or delivered into interstate commerce"). A product subject to premarket review must be denied if: ''(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health; (B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 906(e); (C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular." 21 U.S.C. § 387j(c)(2). A determination of whether a product is appropriate for the protection of the public health turns on ''(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products." 21 U.S.C. § 387j (c)(4).

When it deemed ENDS subject to its authority, the FDA determined that ENDS must "meet all the requirements for a premarket authorization in section 910 of the FD&C Act." 21 C.F.R. 28998. ENDS manufacturers who market their products without premarket authorization are doing so "without FDA authorization." 21 C.F.R. 29010. Although initially set to begin in 2018, after a flurry of lobbying by Defendant,[11] the FDA pushed the date back to 2022.

[11] *See, e.g.,* http://disclosures.house.gov/ld/ldxmlrelease/2017/Q4/300927296.xml; http://disclosures.house.gov/ld/ldxmlrelease/2017/Q3/300915568.xml.

Because Defendant has not undergone premarket approval, which the FDA estimates will cost in excess of $2,000,000 and will take thousands of hours for manufacturers to complete, there has been no determination that its products are "appropriate for the protection of the public health," or whether Puff Bar's labels are "false or misleading in any particular." 21 U.S.C. § 387j(c)(2)(A), (C). The FDA has not assessed "the increased or decreased likelihood that existing users of tobacco products will stop using such products," or "the increased or decreased likelihood that those who do not use tobacco products will start using such products." 21 U.S.C. § 387j(c)(4). It would be inconsistent with the Congressional intent behind the TCA to give Defendant the benefit of federal preemption for its labels, even though no federal agency has reviewed and approved those labels.

B. Plaintiff's Claims are Well-Pled Under The New Jersey Product Liability Act.

Under the New Jersey Product Liability Act ("PLA"), "[a] manufacturer or seller of a product shall be liable . . . only if the claimant proves . . . that the product causing the harm was not reasonably fit, suitable or safe for its intended purpose because it: . . . b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner" thereby recognizing design defect and failure to warn claims. N.J. Stat. Ann. §2A:58C-2. Plaintiffs' SAC adequately plead both claims.

Plaintiffs have alleged sufficient facts to state a claim for relief that is facially plausible. Akin to Plaintiffs' claims in the instant case are those pending against JUUL Labs, Inc. ("JUUL"). Among the various claims against JUUL, an electronic cigarette like Puff Bar, are allegations that it is defective, lacked adequate warnings, and violated consumer protection statutes. In *Colgate*, JUUL filed a Motion to Dismiss all of the plaintiffs' causes of action—including plaintiffs' strict liability claims. [*Colgate* DE 40]. Judge Orrick entered an Order denying virtually all of JUUL's grounds to dismiss the complaint. *See, e.g.*, [*Colgate* Doc. 66] ("I find that under the consumer expectations test, plaintiffs have stated a claim for design defect …."); *see also* [*Colgate* Doc. 139,

at 27] ("Plaintiffs have *plausibly stated a claim for manufacturing and design defect*. They have sufficiently alleged that JUUL's products are more addictive than necessary to provide an alternative to combustible cigarettes and that the risk of higher levels of addiction do not outweigh the benefits of a nicotine formulation that the body absorbs at twice the rate of a pack of combustible cigarettes with the same amount of nicotine.") (emphasis added).

1. Plaintiff Has Sufficiently Alleged a Failure to Warn Claim.

Under the PLA, Plaintiff claims that the product "failed to contain adequate warnings or instructions." N.J. Stat. Ann. § 2A:58C-2.

Defendant incorrectly asserts that Puff Barr is insulated from potential liability for its failure to warn since the harm it posed was a result of an "unavoidably unsafe aspect of the product". *Id.* § 2A:58C-3. As a matter of law, the alleged unavoidableness or obviousness of a danger is reserved for disposition at trial on a full factual record, not in a motion to dismiss on the pleadings. *Kimco Staffing Servs. v. Wolverine World Wide, Inc.*, 2015 U.S. Dist. LEXIS 187256, at *7 (C.D. Cal. July 22, 2015) (denying motion to dismiss); *Mariscal v. Graco, Inc.*, 52 F. Supp. 3d 973, 990 (N.D. Cal. 2014) (denying summary judgment on "whether Plaintiff can be charged with knowledge of the dangerous propensity" of product because, among other reasons, "adequacy of a warning is usually a question of fact for the jury"); *Ybarra v. Overstock*, 2010 U.S. Dist. LEXIS 150266, at *6N8 (S.D. Cal. Feb. 1, 2010); *Fellner v. Tri-Union Seafoods, L.L.C.*, 2010 U.S. Dist. LEXIS 36195, at *25N28 (D.N.J. Apr. 13, 2010) (collecting authority from various state and federal courts for the proposition that determining an obvious danger "is typically an issue of fact that is not appropriately resolved on the pleadings."); *Metzgar v. Playskool Inc.*, 30 F.3d 459, 465-66 (3d Cir. 1994) (collecting authority for the same).

Even if the Court were to credit Defendant's argument, "the obviousness of potential danger cuts against [Puff Bar]," because Defendant marketed and sold its e-cigarettes as a safe

alternative to traditional cigarettes. *See Lovett v. Omni Hotels Mgmt. Corp.*, 2016 U.S. Dist. LEXIS 25480, at *22–25 (N.D. Cal. Feb. 29, 2016) (denying summary judgment on failure to warn claim because obviousness of the risk involved only confirmed plaintiff's theory that the defendant should have done more to mitigate the known risk with a warning).

Moreover, factually, it is reasonable to infer that end users would not attribute the same risks to Puff Bar e-cigarettes as traditional cigarettes, given that: (1) Puff Bar is sold in flavors including "Sour Apple," "cool mint," "Blue Razz," and "Pink Lemonade"—flavors which Congress banned in cigarettes,[12] and (2) Puff Bar products use nicotine-salt which minimizes harshness or throat hit, thereby appealing to nonsmokers. *See Liriano v. Hobart Corp.*, 700 N.E.2d 303 (1998) ("[T]he open and obvious defense generally should not apply when there are aspects of the hazard which are concealed or not reasonably apparent to the user."); *Evans v. Lorillard Tobacco Co.*, 990 N.E.2d 997, 1022–24 (Mass. 2013) (reasonable jury could find that the risks of cigarette smoking were not obvious even after they warned that cigarettes may be hazardous to health because, among other reasons, cigarette manufacturers "engaged in a calculated effort through advertising and public statements" to cast doubt on the risks").

Defendant's statement that a Puff Bar is equivalent to a pack of cigarettes is also insufficient because, among other things, Plaintiffs have alleged that a Puff Bar delivers a much more potent, dangerous dose of nicotine. *See Tompkin v. American Brands*, 219 F.3d 566, 572 (6th Cir. 2000) ("The 'common knowledge' requirement is emasculated if a defendant may show merely that the public was aware that a product presented health risks at some vague, unspecified, and undifferentiated level."). Moreover, unlike in the case of cigarettes, where the user retains the package to carry the cigarettes and is likely to see the warning every time she takes out a cigarette,

[12] 21 U.S.C. § 387g.

the Puff Bar package plays no functional role and would be discarded soon after purchase; no warning appears on the device itself.

2. Plaintiffs' Design Defect Claims Are Well-Pled.

The PLA provides that a product manufacturer or seller shall not be liable if: (i) "[t]he characteristics of the product are known to the ordinary consumer or user," (ii) "the harm was caused by an unsafe aspect of the product that is an inherent characteristic of the product," and (iii) that inherent, unsafe aspect "would be recognized by the ordinary person who uses or consumes the product with the ordinary knowledge common to the class of persons for whom the product is intended." N.J. Stat. Ann. § 2A:58C-3(a)(2).

Defendant inaccurately suggests that Plaintiff's design defect claim is solely based on the fact that Puff Bar products contain nicotine and that nicotine is harmful. Plaintiffs claim goes far beyond this, alleging that Puff Bar is delivering doses of nicotine at levels two-three times higher than those in other electronic cigarettes and combustible cigarettes, and the dangers this nicotine consumptions poses, all while consumers were told that a single product contains an amount of nicotine about equal to a pack of cigarettes, and otherwise perceive e-cigarettes to be a healthier alternative to traditional cigarettes. *See, e.g.*, SAC, ¶¶ 11, 38, 115, 136, 140. Thus, this "unsafe aspect", the nicotine potency of the Puff Bar product, was unknown and could not have been recognized by the consumer or user. As such, Plaintiffs' claim should proceed under the PLA.

In *Colgate*, the Court denied JUUL's motion to dismiss for failure to state a claim for design defect. [*Colgate* Doc. 66, at 15] ("I find that under the consumer expectations test, plaintiffs have stated a claim for design defect . . . JUUL's motion to dismiss plaintiffs' design defect claim is denied."). The Court similarly denied JUUL's Second Motion to Dismiss in *Colgate* as to the strict products liability claims. [*Colgate* Doc. 139, at 27] ("Plaintiffs have plausibly stated a claim for manufacturing and design defect. They have sufficiently alleged that JUUL's products are

more addictive than necessary to provide an alternative to combustible cigarettes and that the risk of higher levels of addiction do not outweigh the benefits of a nicotine formulation that the body absorbs at twice the rate of a pack of combustible cigarettes with the same amount of nicotine.").

C. Plaintiffs' Request for Injunctive Relief Is Based on Plausible Causes of Action.

Because Plaintiffs' above-referenced claims survive Defendant's Motion to Dismiss, Plaintiffs' request for injunctive relief necessarily survives dismissal as well.

III. CONCLUSION

For the reasons identified above, Plaintiffs respectfully request that this Court Deny Defendant's Motion to Dismiss Plaintiff's Second Amended Complaint.

DATED: November 2, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 2, 2020, I served a copy of the foregoing on the Clerk of Court by CM/ECF, which will provide automatic notification to all parties and counsel of record.

By: */s/ Jeffrey L. Haberman*
Jeffrey L. Haberman, Esq.